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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,978	07/16/2003	K. Roger Aoki	16952CON1DIV11	2159

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EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,978	AOKI ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed, 10-12-05, is acknowledged. Claim 18 and 29 were amended. Claims 18, 21-29 are pending in this application.

2. All rejections made in the previous office action and not cited here are hereby withdrawn.

Double Patenting

Maintained Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 18, 21, 22-27 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,887,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Applicants argue that the practice of double patenting in commonly owned application is to prevent different expiration dates covering nearly identical subject matter. "The present double patenting rejection is improper because he claimed invention either has the same expiration date as that of the cited patents, or is not obvious over the claims of the cited patent (and vice versa)."

Applicants arguments have been filed but have not been found persuasive.

First, Applicants state that the instant application is not "obvious over the claims of the cited patent." However, Applicants have not provided any basis (emphasis added) to support this contention. It is maintained for the reasons set forth the previous office action the patent and the instant application are obvious over one another.

Second, "The use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public. In re Jentoft, 392 F.2d 633, 157 USPQ 363 (CCPA 1968); In re Eckel, 393 F.2d 848, 157 USPQ 415 (CCPA 1968); and In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967)." Further, "There are at least two reasons for insisting upon a terminal disclaimer to overcome a nonstatutory double patenting rejection in a continuing application subject to a 20- year term under 35 U.S.C. 154(a)(2). First, 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process.
Thus, 35 U.S.C. 154 does not ensure that any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will necessarily expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). Second, 37 CFR 1.321(c)(3) requires that a terminal disclaimer filed to obviate a nonstatutory double patenting rejection >based on commonly owned conflicting claims< include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection. 37 CFR 1.321(d) sets forth the requirements for a terminal disclaimer where the claimed invention resulted from activities undertaken within the scope of a joint research agreement. These requirements serve to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same

patentable invention. See, e.g., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Not insisting upon a terminal disclaimer to overcome a nonstatutory double patenting rejection in an application subject to a 20-year term under 35 U.S.C. 154(a)(2) would result in the potential for the problem that 37 CFR 1.321(c)(3) was promulgated to avoid. Accordingly, a terminal disclaimer under 37 CFR 1.321 is required in an application to overcome a nonstatutory double patenting rejection, even if the application was filed on or after June 8, 1995 and claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the filing date of the patent or application which forms the basis for the rejection." MPEP 804.02.

Rejection is maintained.

New Grounds For Rejections

4. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,113,915 in view of Schantz et al. and Johnson. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G and the dosage amount can be between 10^{-3}U/kg to 60U/kg (see claim 2 and 3), and more specifically 1U/kg to

20U/kg (see claims 8) . The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for local administration, both Schantz et al. and Johnson et al. teach the effectiveness of botulinum toxin for local denervation (see 80-82 of Schantz et al. and Johnson col. 1). Since the botulinum toxin has an effect on local muscular denervatoin, it would have been obvious to use the botulinum toxin, as claimed in US patent and administer it locally. On would have been motivated to do so, so as to get immediate effect on the local muscle.

Different Inventors, Common Assignee, Obvious Inventions, No Evidence of Common Ownership at Time of Invention

1. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,113,915. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 2).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,113,915, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or

(g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

2. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,235,289 in view of Schantz et al. and Johnson. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G (see claim 2 and 3). The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis and the dosage claimed.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for the dosage, although the US Patent does not claim the specific dosage as the instant application, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. Thus, one would be motivated to find the optimum dosage to treat muscle pain using botulinum toxin.

As for local administration, both Schantz et al. and Johnson et al. teach the effectiveness of botulinum toxin for local denervation (see 80-82 of Schantz et al. and Johnson col. 1). Since the botulinum toxin has an effect on local muscular denervatoin, it would have been obvious to use the botulinum toxin, as claimed in US patent and administer it locally. On would have been motivated to do so, so as to get immediate effect on the local muscle.

Different Inventors, Common Assignee, Obvious Inventions, No Evidence of Common Ownership at Time of Invention

3. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,235,289. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 4).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,235,289, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

4. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,333,037 in view of Schantz et al. and Johnson et al (US 5,696077). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G and the dosage amount can be between 10^{-3}U/kg to 60U/kg (see claim 2 and 3), and more specifically 1U/kg to 20U/kg (see claims 8) . Note that this dosage ranger significantly overlaps the dosage range claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis and administration of botulinum toxin to muscles.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for local administration, both Schantz et al. and Johnson et al. teach the effectiveness of botulinum toxin for local denervation (see 80-82 of Schantz et al. and Johnson col. 1). Since the botulinum toxin has an effect on local muscular denervatoin, it would have been obvious to use the botulinum toxin, as claimed in US patent and administer it locally. On would have been motivated to do so, so as to get immediate effect on the local muscle.

Different Inventors, Common Assignee, Obvious Inventions, No Evidence of Common Ownership at Time of Invention

5. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,333,037. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 6).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,333,037, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

6. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,372,226 in view of Schantz et al. and Johnson et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intrathecal or intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G and the dosage amount can be between -3U/kg to 60U/kg (see claim 3) . Note that this dosage ranger significantly overlaps the dosage range claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for local administration, both Schantz et al. and Johnson et al. teach the effectiveness of botulinum toxin for local denervation (see 80-82 of Schantz et al. and Johnson col. 1). Since the botulinum toxin has an effect on local muscular denervatoin, it would have been obvious to use the botulinum toxin, as claimed in US patent and administer it locally. On would have been motivated to do so, so as to get immediate effect on the local muscle.

Different Inventors, Common Assignee, Obvious Inventions, No Evidence of Common Ownership at Time of Invention

7. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,372,226. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 8).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,372,226, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

Anish Gupta 1/9/08
Patent Examiner